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Pesticide Assessment Guidelines, Subdivision E Hazard Evaluation: Wildlife and Aquatic Organisms, Series 71-3. Wild Mammal Toxicity Test. Addendum 3 on Data Reporting

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ADDENDUM 3 to Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms (EPA-540/9-82-024 and NTIS Order Number PB83-153908), October, 1982

16. Abstract (Limit: 200 words)

The Data Reporting Guideline (DRG) for Wild Mammal Toxicity Test, Series 71-3, gives guidance to pesticide registrants on the format for their study report so that the Agency can review it efficiently. It clarifies sections in the existing Pesticides Assessment Guidelines, Subdivision E, on data reporting and provides an outline for study reports and describes the topics and the order in which they should be addressed. Formats for the presentation of mortality, weight and food consumption data in tables is also provided. Data submitters can use the DRG in preparing their reports for submission to EPA to meet 40 CFR 158 requirements for the registration of pesticides.

The DRG for Series 71-3, Wild Mammal Toxicity Test is only one of a number of DRG's published by the National Technical Information Service as an addendum to Subdivision E of the Pesticide Assessment Guidelines.

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PESTICIDE ASSESSMENT GUIDELINES

SUBDIVISION E

HAZARD EVALUATION:

WILDLIFE AND AQUATIC ORGANISMS

Series 71-3

Wild Mammal Toxicity Test

ADDENDUM 3 ON DATA REPORTING

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Subdivision E - Wild Mammal Toxicity Test

Table of Contents of Addendum

Discussion

Introduction 2

Response to Public Comments 2

Guideline

Title/Cover Page 2

Table of Contents 2

I. Summary/Introduction 3

II. Materials/Methods 3

III. Discussion/Results 6

IV. Conclusion 6

V. References 6

Tables 7

PESTICIDE ASSESSMENT GUIDELINES

WILDLIFE AND AQUATIC ORGANISMS

Wild Mammal Toxicity Test

Subdivision E, Series 71-3

DATA REPORTING

INTRODUCTION

A. Purpose

To provide a data reporting format for a study of a wild mammal toxicity test.

B. Objective

This Data Reporting Guideline is designed to aid the petitioner/registrant in generating reports which are compatible with the Agency's review process. Data submitters are encouraged to submit complete reports following this guidance for efficient review by the Agency. This guidance pertains to the substance of the data report. PR Notice 86-5, effective on November 1, 1986 (available from the Registration Support and Emergency Response Branch, Office of Pesticide Programs, US EPA), pertains to the physical formating of reports (which are referred to as "studies") and submittal packages. Some of the requirements in PR Notice 86-5 are mandatory.

RESPONSE TO PUBLIC COMMENTS

There were no comments concerning this specific guideline in response to the request for public comments announced in the FEDERAL REGISTER notice of October 15, 1986 (51 FR 36753).

GUIDELINE

The following describes the order and format for a study report item by item.

TITLE/COVER PAGE

Refer to PR Notice 86-5.

TABLE OF CONTENTS

The Table of Contents should indicate the overall organization of the

study, including table and figures. It must follow the title, data confidentiality, and GLP (if appropriate) pages as described in PR Notice 86-5.

I. SUMMARY/INTRODUCTION

A. Sponsor: (name of study owner);

B. Name(s) of principal investigator(s);

C. Location of study;

D. Location of raw data and final report;

E. Material: (Common/trade name);

F. Subject: (final or draft report, eight-day dietary LC_{50});

G. Test Doses: (control, concurrent vehicle control, #, #, #, #, # ppm);

H. Test Dates: Initiation (Date test started), and Termination (Date of last day of observation);

I. Length of study: (days);

J. Results: (LC_{50} value, 95% confidence limits, and no-observed-effects level);

K. Test Material: (chemical name, formulation, and percent of active ingredient);

L. Test Species/Strain: (both common and scientific name);

M. Source of Mammal: (company name, address, or captive/wild);

N. Weight and physical condition at the initiation of study.

II. MATERIAL/METHODS

This section is a narrative which would include the following items:

A. <u>Test Substance</u>

1. Identification (this information may be provided by the laboratory or sponsor):

a. Chemical name;
b. Composition (qualitative and quantitative description);
c. Percent active ingredient;
d. Molecular structure;
e. Source, lot and batch number; and
f. Identity and percent composition of impurities in the test substance.

2. Preparation of test material (control/treatment):

   a. Vehicle used to dissolve test material (if used);
   b. Amount of vehicle added to the control (if used);
   c. Describe method used to get test material into diet;
   d. Solubility of test material in ppm; and
   e. Total amount of test material used.

B. Test Mammal

1. Rationale for selection of species if the species used is different than those exposed to test substance's use pattern:

   a. Test species name (both common and scientific); and
   b. History of test organisms (strain, disease, and treatment).

2. Description of any pretest conditioning:

   a. Health:

      1. Sickness;
      2. Injuries;
      3. Abnormalities;
      4. Name of medication (if used); and
      5. Pretest diet;

   b. Quarantine:

      Number of days mammals were held.

3. Size/age/physical condition:

   a. Age of each animal and how determined;
   b. Size (is weight of any animal more than $\pm$ 20% of mean weight); and
   c. Physical condition of test animals.

4. Acclimation:

   a. Daily food consumption;
   b. Daily behavior of test animal;
   c. Body weights (beginning and end of acclimation);
   d. Diet used;
   e. Source of animal food and water;
   f. Dimensions of pen(s); and
   g. Length of photoperiod (in days).

C. Testing Facility

1. Physical:

   a. Size and construction of pen or cage with description of any special features;

b. Location of and availability of drinking water;
c. Ventilation system in the laboratory; and
d. Identification of any special laboratory equipment unique to the study.

2. Biological:

a. Daily temperature measurements;
b. Daily relative humidity measurements;
c. Daily photoperiod; and
d. Daily laboratory air exchange rate.

D. Test Exposure Parameters

1. Range Finding Test:

a. Number of animals used;
b. Method used to determine dose levels;
c. Raw data for determining the end point;
d. Treatment and observation period; and
e. Any statistical analysis utilized.

E. Definitive Test

1. Number of animals used and a rationale for using less than ten animals per treatment level, if appropriate;
2. Number of treatment levels;
3. Name of vehicle used;
4. References to toxicity of vehicle;
5. Were controls and vehicle controls used;
6. Raw mortality or effects data for each group;
7. Duration of treatment and observation periods;
8. Statistical analysis of the data;
9. Methodology for dosing;
10. Methodology for treatment diet preparation;
11. Toxicologically related behavioral change;
12. Analysis of basal diet;
13. Criteria for end point of study;
14. Number of animals of each sex of animal tested;
15. Test diet; and
16. Methods used to calculated LC_{50}.

F. Necropsies

1. No-effects-level (how determined);
2. Maximum-acceptable-tolerated-concentration (MATC); and
3. Gross and histological necropsies.

G. Body Weight and Food Consumption

1. Daily body weight by animal and level;
2. Total daily food consumption by animal and level; and

3. Mean body weight for each test and control group at initiation and termination of test.

H. Observation

1. Signs of intoxication, temporal onset, duration, and concentrations that showed effects;
2. The no-effect-level; and
3. Slope of dose-response line.

I. Statistical Analysis

1. Cite references (author, title, journal, number, page, etc.); and
2. Rationale for deviations from the cited method.

III. DISCUSSION/RESULTS

A. LC_{50} in ppm with 95% confidence limits, no-observed-effect level, slope of the dose response line, if the method provides a slope. (Optional graphs, printouts, and other calculations may be attached to the report).

B. Detailed description of the nature, incidence, time of occurrence, severity, and duration of all observed toxic effects, including death and any other abnormal or unusual signs and symptoms. For example, report any specific signs of intoxication associated with death and the time of onset and remission of toxic signs. Also report marked observations of fecal material and urine.

C. Gross pathological changes as noted by gross necropsies examination.

D. Describe control mammal parameters, behavior, and general health.

E. Indicate the test procedures which deviate from the EPA guidelines and provide a rationale for the change.

F. Report any other items related to the study which may be of value in hazard assessment or evaluation of the study, e.g. regurgitation.

IV. CONCLUSIONS

This is a summation of the above section Discussion/Results.

V. REFERENCES

For instance, any references which were used in the development of the study design must be cited.

TABLE 1

CUMULATIVE MORTALITIES OF (Test species name) Exposed

TO (Chemical) FOR FIVE DAYS

Concentration	Number Dead/Number Exposed								
	Day of Death								
ppm	0	1	2	3	4	5	6	7	8
xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
xx	xx	xx	xx	xx	xx	xx	xx	xx	xx

TABLE 2

CUMULATIVE MORTALITIES OF (Test species name) Exposed

TO (Chemical) FOR EIGHT DAYS

Control	Number Dead/Number Exposed								
	Day of Death								
ppm	0	1	2	3	4	5	6	7	8
0	xx	xx	xx	xx	xx	xx	xx	xx	xx
0	xx	xx	xx	xx	xx	xx	xx	xx	xx
0	xx	xx	xx	xx	xx	xx	xx	xx	xx
0	xx	xx	xx	xx	xx	xx	xx	xx	xx
0	xx	xx	xx	xx	xx	xx	xx	xx	xx

TABLE 3

DAILY BODY WEIGHT OF (Test species name) EXPOSED TO (Chemical)

FOR (#) DAYS

Material	Conc. ppm	Body Weight/Animal/Day 0	1	2	3	4	5	6	7	8
Chemical's common name	x	x	x	x	x	x	x	x	x	x
	x	x	x	x	x	x	x	x	x	x
	x	x	x	x	x	x	x	x	x	x
	x	x	x	x	x	x	x	x	x	x
	x	x	x	x	x	x	x	x	x	x
Control	0	x	x	x	x	x	x	x	x	x

TABLE 4

DAILY ESTIMATED FOOD CONSUMPTION OF (Test species name) EXPOSED TO

(Chemical) FOR EIGHT DAYS

Material	Conc. PPM	Food Consumption/Animal/Day 0	1	2	3	4	5	6	7	8
Chemical's common name	x	x	x	x	x	x	x	x	x	x
	x	x	x	x	x	x	x	x	x	x
	x	x	x	x	x	x	x	x	x	x
	x	x	x	x	x	x	x	x	x	x
	x	x	x	x	x	x	x	x	x	x
Control	0	x	x	x	x	x	x	x	x	x